

Claims

What is claimed is:

1. A composition for improving the bioavailability of a drug comprising at
5 least one poorly bioavailable drug dissolved in an effective amount of menthol.

2. The composition according to claim 1, wherein the poorly bioavailable
drug is a drug with low aqueous solubility, a drug metabolized by cytochrome P450, a
drug expelled from cells by the P-glycoprotein pump, or a drug metabolized via
10 glucuronidation.

3. The composition according to claim 2, wherein the drug with low aqueous
solubility is a drug having a water solubility of less than about 20 mg/ per milliliter of
water.

15 4. The composition according to claim 1, wherein the drug is cyclosporine,
atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pravastatin, simvastatin,
paclitaxel, fenofibrate, itraconazole, bromocriptine, carbamazepine, diazepam, paclitaxel,
etoposide, camptothecin, danazole, progesterone, nitrofurantoin, estradiol, estrone,
20 oxfendazole, proquazone, ketoprofen, nifedipine, verapamil, or glyburide.

5. The composition according to claim 1, wherein the drug is cyclosporine,
atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pravastatin, simvastatin, or
paclitaxel.

25 6. The composition according to claim 1, wherein the compound is
simvastatin, paclitaxel, or cyclosporine.

7. A method for improving the bioavailability of a drug comprising
30 dissolving the drug in an effective amount of menthol.

8. A method for improving the bioavailability of a drug comprising
dissolving at least one poorly bioavailable drug in an effective amount of menthol.

9. The method according to claim 8, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

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10. The method according to claim 8, further comprising administering the composition to a mammal.

11. The method according to claim 8, wherein the amount of menthol is
10 sufficient to increase the oral bioavailability of the drug by an amount represented by an about 10% or more increase in the average area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

12. The method according to claim 9, wherein the amount of menthol is about
15 60% to 99% by weight.

13. A method for reducing the variability of the bioavailability of a drug comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol.

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14. The method according to claim 13, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

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15. The method according to claim 13, further comprising administering the composition to a mammal.

16. The method according to claim 13, wherein the amount of menthol is
30 sufficient to decrease the variability in the drug's bioavailability by about 10% or more of the relative standard deviation (CV%) of the area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC.

17. A method for increasing the extent of time that a drug provides a therapeutically significant concentration in blood or plasma comprising dissolving at least one poorly bioavailable drug in an effective amount of menthol.

5 18. The method according to claim 17, wherein the poorly bioavailable drug is a drug with low aqueous solubility, a drug capable of being metabolized by cytochrome P450, a drug capable of being expelled from cells by the P-glycoprotein pump, or a drug capable of being metabolized via glucuronidation.

10 19. The method according to claim 17 wherein the amount of menthol is sufficient to extend the time that the drug provides a therapeutically significant concentration in blood or plasma by one hour or more.